# **Complete Summary**

#### **GUIDELINE TITLE**

Prevention and treatment of pediatric obesity: an Endocrine Society clinical practice guideline.

# **BIBLIOGRAPHIC SOURCE(S)**

August GP, Caprio S, Fennoy I, Freemark M, Kaufman FR, Lustig RH, Silverstein JH, Speiser PW, Styne DM, Montori VM. Prevention and treatment of pediatric obesity: an Endocrine Society clinical practice guideline based on expert opinion. J Clin Endocrinol Metab 2008 Dec;93(12):4576-99. [269 references] PubMed

#### **GUIDELINE STATUS**

This is the current release of the guideline.

Endocrine Society clinical guidelines are valid for 3 years, after which time they are revised.

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

# SCOPE

## DISEASE/CONDITION(S)

Pediatric obesity

## **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness Counseling Diagnosis Prevention Risk Assessment Screening Treatment

#### **CLINICAL SPECIALTY**

Cardiology
Endocrinology
Family Practice
Internal Medicine
Medical Genetics
Nutrition
Pharmacology
Preventive Medicine
Psychology
Surgery

## **INTENDED USERS**

Advanced Practice Nurses Dietitians Nurses Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

- To provide practice guidelines for the treatment and prevention of pediatric obesity
- To summarize information concerning:
  - The seriousness of pediatric obesity and overweight
  - The diagnostic criteria
  - The available treatments and when to apply them
  - The available measures to prevent overweight and obesity

# **TARGET POPULATION**

Overweight and obese children and adolescents

# INTERVENTIONS AND PRACTICES CONSIDERED

# Screening/Diagnosis/Risk Assessment

- 1. Determination of Body mass index (BMI) and waist circumference
- 2. Laboratory testing (e.g., plasma glucose, lipids, triglycerides, alanine aminotransferase)
- 3. Homeostasis model assessment of insulin resistance (HOMA-IR)
- 4. Blood pressure
- 5. Genetic testing
- 6. Evaluation of co-morbidities and complications

- 7. Family history
- 8. Patient medical history
- 9. Environmental history

#### Treatment

- 1. Lifestyle modifications
  - Dietary
  - Physical activity
  - Behavioral
- 2. Pharmacotherapy (sibutramine, orlistat, metformin, octreotide, leptin, topiramate, growth hormones)
- 3. Bariatric surgery

# **Prevention/Counseling**

- 1. Promotion of breastfeeding
- 2. Promotion of and participation in efforts to educate patients, parents and the community on healthy dietary and activity habits
- 3. Advocacy of healthy regulatory policies in school districts and communities
- 4. Calorie reduction
- 5. Daily exercise

# **MAJOR OUTCOMES CONSIDERED**

- Changes in body composition and body mass index (BMI)
- Incidence of obesity-related co-morbidities (pre-diabetes, diabetes mellitus, dyslipidemia, hypertension, nonalcoholic fatty liver disease)
- Physical, cognitive, and psychosocial health
- Adverse reactions to treatment
- Mortality

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

# **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

**Note from the National Guideline Clearinghouse (NGC)**: The Endocrine Society's Guideline Task Force on Pediatric Obesity commissioned two systematic reviews (see the "Availability of Companion Documents" field) to support their guidelines on prevention and treatment of pediatric obesity.

# **Search Strategy**

An experienced reference librarian designed and conducted an electronic search of all published literature indexed in the electronic databases MEDLINE, ERIC, EMBASE, CINHAL, PSYCInfo, DISSERTATION abstracts, Science Citation Index, Social Science Citation Index, and the Cochrane CENTRAL Database of controlled clinical trials, from each database's inception until February 2006. Researchers used terms (both words and terms in the controlled vocabulary of each database) to cover the following concepts: overweight and obesity in children, behavioral modification, nonpharmacological treatments, prevention, and randomized trials.

The database search was supplemented with manual review of the reference lists of included articles, review articles, and expert suggestions. Two reviewers, working in duplicate and independently, screened all abstracts and titles as well as all full text publications for eligibility. In cases of disagreement between the reviewers, a third member of the research team not involved in the initial assessment adjudicated the study after reviewing the stated reasons for the initial assessment and the full text of the report. For the prevention review, studies focused exclusively on obese children were excluded; these studies were included in the treatment review. Otherwise, these two reviews share common search and selection processes but no common analyses.

#### NUMBER OF SOURCE DOCUMENTS

#### **Prevention Review**

The search yielded 1162 potentially eligible abstracts. Investigators also considered 64 additional articles from review of reference lists from relevant reviews and guidelines and from input from the Pediatric Obesity Task Force members. They found 36 eligible randomized controlled trials (RCTs); of these, three reported on population reported in another included RCT, and two were deemed ineligible after author contact and clarification. Of the remaining RCTs, investigators were able to obtain complete data from 34 RCTs for body max index (BMI), of which 29 RCTs had complete data for at least one of the behavioral endpoints.

# **Treatment Review**

After searching the electronic databases, investigators identified 1162 abstracts, of which 263 were deemed relevant by title and abstract alone. Also, they found an additional 65 articles from review of references from relevant reviews and guidelines and from input from the obesity task force members. After review of 328 full-text articles for treatment and prevention of pediatric obesity, 75 articles were deemed eligible for the review on treatment of pediatric obesity. One additional trial we detected in the U.S. Food and Drug Administration (FDA) website and considered unpublished was indeed published at the time of the final draft of this report and was included; in all, 61 trials had complete data to include in meta-analyses.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

# **Quality of the Evidence**

- **+000** Denotes very low quality evidence
- **++00** Denotes low quality evidence
- +++0 Denotes moderate quality evidence
- ++++ Denotes high quality evidence

#### METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials Review of Published Meta-Analyses Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC)**: The Endocrine Society's Guideline Task Force on Pediatric Obesity commissioned two systematic reviews (see the "Availability of Companion Documents" field) to support their guidelines on prevention and treatment of pediatric obesity.

## **Prevention Review**

#### **Quality Assessment**

Working independently and in duplicate, reviewers ascertained the reported quality of eligible randomized controlled trials (RCTs). They assessed the adequacy of concealment of allocation (chance-adjusted interobserver agreement; kappa = 0.73), blinding of patients to allocation (kappa = 1.0) or to the study hypotheses (kappa = 1.0) as well as blinding of health-care providers (kappa = 0.86) and data collectors (kappa = 0.83). They also assessed whether the analyses were based on the intention to treat principle (kappa = 1.0) and the extent of loss of follow-up, i.e., proportion of patients in whom the investigators were not able to ascertain outcomes.

#### **Data Abstraction**

Working in duplicate and using a standard abstraction form, researchers abstracted the following data from each study: year and journal of publication, description of the study including setting and location, eligibility criteria, duration of study, and elapsed time from subject randomization to assessment of outcomes. They also collected information on participants, including sex, ethnicity, age, and other relevant demographic details and abstracted details on the nature of intervention and control.

The researchers extracted the interventional components/strategies underlying each intervention as described in each trial according to a predefined framework.

Specifically, they identified which of informational, cognitive, behavioral, environmental, or social support components (see Table 1 in the prevention systematic review [see the "Availability of Companion Documents" field) were included in the description of the interventions.

Informational components included passive information (kappa = 0.82) and education (kappa = 0.89). Cognitive components included general cognitive strategies (kappa = 0.82), goal setting (kappa = 0.85), and problem solving/relapse prevention (kappa = 0.84). Behavioral components included reminders and prompts for desired behaviors (kappa = 0.82), skill building, practice and rehearsal (kappa = 0.95), monitoring and feedback (kappa = 0.66), and reinforcement for behavior (kappa = 1.0). Environmental components consist of actual physical changes made to facilitate desired changes in behavior and to inhibit undesired changes by changing the environment of the home (kappa = 0.55), school (kappa = 0.95), and community (kappa = 0.71). Parental support strategy components reflected the active involvement of primary parents but also included other significant caregivers in the delivery of the intervention (kappa = 0.73).

Finally, the researchers collected outcome data (end of study [preferred] or change from baseline) on each lifestyle variable and body mass index (BMI) for the longest period of follow-up for which data were available and where there was not excessive (>20%) loss to follow-up and where patients were still exposed to treatment or control. Missing data were calculated using standard procedures recommended in the Cochrane Handbook. The researchers contacted authors and requested information when data were measured but not adequately reported. Response rate from author contact was approximately 30%.

## **Quantitative Data Synthesis**

Researchers determined the effect sizes (standardized mean differences) and 95% confidence interval (CI) for the difference between arms (treatment vs. control) for each of the four behavioral targets and for BMI by dividing the mean difference by the pooled standard deviation (SD) between arms with adjustment for small samples (Hedges g), as implemented in Review Manager (RevMan) version 4.2 for Windows (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). When data were in the form of odds ratios or counts, metaanalyses were conducted using the generic inverse variance method as implemented in RevMan. The researchers quantified the extent of the variability observed that could be accounted by true between-study differences rather than chance using the I $^2$  statistic.

## **Subgroup Analyses**

Preplanned subgroup analyses was explored by grouping RCTs by quality (loss to follow-up <20%), by the age (child or adolescent) and sex of the study population, by whether the trial was described as pilot feasibility or not, by study duration (<3 months, 3–6 months, and >6 months), by outcome measured during treatment or during maintenance, and by whether the intervention was school based. Additional preplanned subgroup analyses explored treatment-subgroup interactions with the type of intervention (cognitive: multiple components or single/no components and goal setting; behavioral: multiple components or

single/no components, reinforcement/rewards, social support, and environmental changes) and whether researchers measured outcomes objectively and with high quality. An example of an objective measure for physical activity would be accelerometer data; an example of high-quality measurement would be moderate to vigorous activity, minutes per week vs. frequency of physical activity in the last week. Subgroup analyses, although planned, were exploratory; adjustments for multiple comparisons were not applied.

## **Treatment Review**

#### **Data Collection**

Working in duplicate, six trained reviewers extracted the following data from each eligible article: year and journal of publication, type of study (e.g., pilot), level of randomization (e.g., community, school, or clinical), participants (age and gender), measure of obesity (BMI, percent overweight, percent fat-free mass, or visceral adiposity), experimental and control interventions (type of intervention, deliverer of intervention, and level and duration of intervention) and results. When authors reported both end-of-study results and change-from-baseline results, end-of-study results were collected assuming that imbalances at baseline between groups were random and would even out as pooled across trials. When possible, mean or variance data were calculated from related information (e.g., reported *t* scores and *P* values, standard error [SE], and CI) using standard procedures recommended in the Cochrane Reviewers' Handbook version 4.2.5 (www.Cochrane.org/resources/handbook/).

# **Quality Assessment**

To ascertain the validity of eligible randomized trials, pairs of reviewers working independently and with substantial reliability (corresponding kappa where appropriate) determined the extent to which trials reported concealment of allocation (kappa = 0.94), blinding of patients (kappa = 0.94) to the provider of intervention (kappa = 0.94) and data collectors (kappa = 1), blinding to the hypothesis (kappa =1), level of randomization (kappa =0.83), and extent of loss to follow-up (i.e., the percentage of patients in whom the investigators were not able to ascertain outcomes).

#### **Author Contact**

Using up to two electronic mail contacts to the corresponding and/or first author of each eligible article, the investigators sought to confirm their data extraction and quality assessment and to request missing information about trial design and quality, study characteristics, or outcome data. The response rate to the requests was 22%.

## **Statistical Analysis**

Meta-analysis

For each analysis, the investigators determined the effect size (standardized mean difference) and 95% CI for the difference between treatment arm and control

arm. The standardized mean difference resulted from dividing the mean difference between arms by the pooled variance between arms with adjustment for small samples (Hedges g) as implemented in Revman 4.2 (Cochrane Collaboration). They considered standardized mean differences of about 0.2 or less as small, about 0.5 as moderate, and about 0.8 or greater as large effect sizes. Randomeffects meta-analysis was used to compare the effects on obesity outcomes of diet alone vs. control, exercise alone vs. control, pharmacological therapy vs. placebo control, and combined lifestyle modifications vs. control. They quantified the extent to which the between-study variability observed was due to true between-study differences (rather than to chance) using the  $\rm I^2$  statistic. Inconsistency was small when  $\rm I^2$  was less than 25%, moderate 25–50%, and large >50%.

## Subgroup Analysis

The investigators performed four subgroup analyses. Several narrative reviews reported that delivering combined lifestyle interventions involving parents or the family was a promising approach to treating obesity; hence, they performed a subgroup analysis comparing the effect of this intervention when delivered to the child or the adolescent and compared its effects when it was delivered with some degree of parental participation. They analyzed combined lifestyle interventions delivered to various age-group-specific targets. Also, they hypothesized that physical activity interventions could have a greater effect on percent body fat than on BMI; hence, they performed a subgroup analysis of these trials by outcome. In addition, they sought to determine whether reduced sedentary behavior and increased physical activity had distinct impact on obesity outcomes. Finally, they tested for a subgroup interaction between the choice of outcome measure (change-from-baseline vs. end-of-study) and the treatment effect, but these tests were not contributory.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

# **Participants**

The Task Force was composed of a chair, selected by the Clinical Guidelines Subcommittee (CGS) of The Endocrine Society, eight additional experts, one methodologist, and a medical writer.

#### **Evidence**

Systematic reviews of available evidence were used to formulate the key treatment and prevention recommendations. The authors used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe both the quality of evidence and the strength of recommendations. The authors used 'recommend' for strong recommendations and 'suggest' for weak recommendations.

#### **Consensus Process**

Consensus was guided by systematic reviews of evidence and discussions during one group meeting, several conference calls, and e-mail communications.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

#### **Strength of Recommendations**

- The number 1 indicates a strong recommendation and is associated with the phrase "The Task Force recommends."
- The number 2 denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

# **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The drafts prepared by the task force with the help of a medical writer were reviewed successively by The Endocrine Society's Clinical Guidelines Subcommittee (CGS), Clinical Affairs Core Committee (CACC), the Lawson Wilkins Pediatric Endocrine Society's Obesity Task Force, and Executive Committee. The version approved by the CGS and CACC was placed on The Endocrine Society's Web site for comments by members. At each stage of review, the Task Force received written comments and incorporated needed changes.

#### **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

Definitions for the quality of the evidence (+000, ++00, +++0, and ++++); the strength of the recommendation (1 or 2), and the difference between a "recommendation" and a "suggestion" are provided at the end of the "Major Recommendations" field.

# **The Problem with Obesity**

The objective of interventions in overweight and obese children and adolescents is the prevention or amelioration of obesity-related co-morbidities (e.g., glucose intolerance and type 2 diabetes mellitus (T2DM), metabolic syndrome, dyslipidemia, and hypertension).

# **Diagnosis of Overweight and Obesity**

The Task Force recommends the use of the Body Mass Index (BMI) (calculated as weight in kilograms divided by height in meters squared), with the Centers for Disease Control and Prevention (CDC) derived normative percentiles, as the preferred method for the diagnosis of the overweight or obese child  $(1 \mid ++00)$ .

The Task Force recommends that a child be diagnosed as overweight if the BMI is in at least the  $85^{th}$  percentile but less than the 95th percentile for age and sex, and as obese if the BMI is in at least the 95th percentile for age and sex (1 | +000).

The Task Force recommends against a routine laboratory evaluation for endocrine causes of obesity in obese children or early to mid-pubertal obese adolescents unless the child's height velocity, assessed in relation to stage of puberty and family background, is attenuated (1 + +00).

The Task Force recommends referral to a geneticist for children whose obesity has a syndromic etiology, especially in the presence of neurodevelopmental abnormalities  $(1 \mid +000)$ .

The Task Force suggests that parents of children who have inexorably gained weight from early infancy and have risen above the 97th percentile for weight by 3 years of age be informed of the availability of melanocortin 4 receptor (MC4R) genetic testing. However, the test is positive in only 2-4% of such patients who are above the 97th percentile for weight and currently will not alter treatment (2 | +000).

The Task Force recommends that children with a BMI in at least the 85th percentile be evaluated for associated co-morbidities and complications (1 | +000). See "Table 1: Screening Tests for the More Common Obesity Co-Morbidities" and Figure 1 "Diagnosis and Management Flow Chart" in the original guideline document for more detailed information.

## **Treatment of Obesity**

# **Lifestyle Recommendations**

The Task Force recommends that clinicians prescribe and support intensive lifestyle (dietary, physical activity, and behavioral) modification for the entire family and the patient in an age-appropriate manner and as the prerequisite for all overweight and obesity treatments for children and adolescents  $(1 \mid +000)$ .

#### Dietary Recommendations

The Task Force recommends that clinicians prescribe and support healthy eating habits such as:

 Avoiding the consumption of calorie-dense, nutrient-poor foods (e.g., sweetened beverages, sports drinks, fruit drinks and juices, most "fast food," and calorie-dense snacks) (1 | ++00). The Task Force suggests that clinicians prescribe and support:

- Controlling caloric intake through portion control in accordance with the Guidelines of the American Academy of Pediatrics [http://pediatrics.aappublications.org/cgi/reprint/117/2/544.pdf] (2 | +000).
- Reducing saturated dietary fat intake for children older than 2 years of age (2 | ++00).
- Increasing the intake of dietary fiber, fruits, and vegetables (2 | +000).
- Eating timely, regular meals, particularly breakfast, and avoiding constant "grazing" during the day, especially after school (2 | +000).

## Physical Activity Recommendations

The Task Force recommends that clinicians prescribe and support 60 min of daily moderate to vigorous physical activity  $(1 \mid ++00)$ .

The Task Force suggests that clinicians prescribe and support a decrease in time spent in sedentary activities, such as watching television, playing video games, or using computers for recreation. Screen time should be limited to 1-2 hours per day, according to the American Academy of Pediatrics ( $2 \mid +000$ ).

## Psychosocial Recommendations

The Task Force suggests that clinicians educate parents about the need for healthy rearing patterns related to diet and activity. Examples include parental modeling of healthy habits, avoidance of overly strict dieting, setting limits of acceptable behaviors, and avoidance of using food as a reward or punishment (2 | +000).

The Task Force suggests that clinicians probe for and diagnose unhealthy intrafamily communication patterns and support rearing patterns that seek to enhance the child's self-esteem  $(2 \mid +000)$ .

# **Pharmacotherapy Recommendations**

The Task Force suggests that pharmacotherapy (in combination with lifestyle modification) be considered if a formal program of intensive lifestyle modification has failed to limit weight gain or to mollify comorbidities in obese children. Overweight children should not be treated with pharmacotherapeutic agents unless significant, severe co-morbidities persist despite intensive lifestyle modification. In these children, a strong family history of Type 2 Diabetes Mellitus or cardiovascular risk factors strengthens the case for pharmacotherapy (2 | +000).

The Task Force suggests that pharmacotherapy be offered only by clinicians who are experienced in the use of anti-obesity agents and are aware of the potential for adverse reactions  $(2 \mid +000)$ .

# **Bariatric Surgery Recommendations**

The Task Force suggests that bariatric surgery be considered only under the following conditions:

- 1. The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- 2. The child has a BMI greater than 50 kg/m<sup>2</sup> or has BMI above 40 kg/m<sup>2</sup> and significant, severe comorbidities.
- 3. Severe obesity and co-morbidities persist despite a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- 4. Psychological evaluation confirms the stability and competence of the family unit.
- 5. There is access to an experienced surgeon in a medical center employing a team capable of long term follow-up of the metabolic and psychosocial needs of the patient and family, and the institution is either participating in a study of the outcome of bariatric surgery or sharing data.
- 6. The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits  $(2 \mid ++00)$ .

The Task Force recommends against bariatric surgery for preadolescent children, for pregnant or breastfeeding adolescents, and for those planning to become pregnant within 2 years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved eating disorder, untreated psychiatric disorder, or Prader-Willi syndrome  $(1 \mid ++00)$ .

# Prevention of Obesity

The Task Force recommends breast-feeding for a minimum of 6 months (1 | ++00).

The Task Force suggests that clinicians promote and participate in efforts to educate children and parents by means of ongoing anticipatory guidance about healthy dietary and activity habits and, further, that clinicians encourage school systems to provide adequate health education courses promoting healthy eating habits  $(2 \mid ++00)$ .

The Task Force suggests that clinicians promote and participate in efforts to educate the community about healthy dietary and activity habits  $(2 \mid +000)$ .

## **Societal Barriers to Implementation**

The Task Force suggests that clinicians advocate:

- For regulatory policies designed to decrease the exposure of children and adolescents to the promotion of unhealthy food choices in the community (e.g., by media advertisements targeting children and adolescents) (2 | +000).
- That school districts ensure that only nutritionally sound food and drinks are available to children in the school environment, including the school cafeteria and alternative sources of food such as vending machines (2 | +000).

- For parental participation in the design of school-based dietary or physical activity programs and that schools educate parents about the rationale for these programs to ensure their understanding and cooperation (2 | +000).
- That community master planners design, redesign, and organize communities to maximize opportunities for safe walking or cycling to school, recreational activity and athletic events, and neighborhood shopping as a means to encourage greater physical activity (2 | +000).
- That clinicians advocate that policymakers provide incentives to ensure that retailers can offer affordable, high-quality fresh fruits and vegetables to all (2 | +000).

## **Definitions:**

## Strength of Recommendations

- **1** Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."
- **2** Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

# **Quality of the Evidence**

- **+000** Denotes very low quality evidence
- ++00 Denotes low quality evidence
- **+++0** Denotes moderate quality evidence
- ++++ Denotes high quality evidence

#### CLINICAL ALGORITHM(S)

A clinical algorithm was provided in the original guideline document (Figure 1) for the diagnosis and management of pediatric obesity.

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

# TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Appropriate prevention and treatment of pediatric obesity

#### **POTENTIAL HARMS**

# Obesity Medications

Potential side effects associated with anti-obesity medications See Table 2 in the original guideline document for details on the side effects of medications proposed for the treatment of obesity.

## Bariatric Procedures

- The Task Force suggests limited use of bariatric surgery that places a relatively higher value on avoiding anatomical and functional changes in developing children, on avoiding unforeseen complications associated with lifelong exposure to these changes, and on avoiding the costs and perioperative complications of these procedures.
- Because of the high morbidity and mortality associated with jejunoileal bypass and the biliopancreatic diversion with duodenal switch, they cannot be recommended for use in children.

## **CONTRAINDICATIONS**

#### **CONTRAINDICATIONS**

- Sibutramine should not be used with other drugs, monoamine oxidase inhibitors
- Metformin should not be used in patients with renal failure or with intravenous contrast.

# **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

- For many issues for which the evidence base is of low or very low quality, the Task Force, nonetheless, elected to make strong recommendations. As noted by Guyatt et al., "The strength of any recommendation depends on the following two factors: the tradeoff between the benefits and risks and burdens; and the quality of the evidence regarding treatment effect...."A category 1 (strong) recommendation can be made when "the tradeoff is clear enough that most patients, despite differences in values, would make the same choice...." A category 2 (weak) recommendation is made when "the tradeoff is less clear, and individual patient values will likely lead to different choices..."
- The Task Force concurs with the statement of Snow et al., "Clinical practice guidelines are guides only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment".
- Clinical Practice Guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The Guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The Guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The

- Guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgment of health care providers and each patient's individual circumstances.
- The Endocrine Society makes no warranty, express or implied, regarding the Guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein.

# **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Clinical Algorithm Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Getting Better Staying Healthy

## **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

August GP, Caprio S, Fennoy I, Freemark M, Kaufman FR, Lustig RH, Silverstein JH, Speiser PW, Styne DM, Montori VM. Prevention and treatment of pediatric obesity: an Endocrine Society clinical practice guideline based on expert opinion. J Clin Endocrinol Metab 2008 Dec;93(12):4576-99. [269 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2008 Dec

## **GUIDELINE DEVELOPER(S)**

The Endocrine Society - Disease Specific Society

# **SOURCE(S) OF FUNDING**

The Endocrine Society

#### **GUIDELINE COMMITTEE**

Pediatric Obesity Task Force

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Task Force Members: Gilbert P. August; Sonia Caprio; Ilene Fennoy; Michael Freemark; Francine R. Kaufman; Robert H. Lustig; Janet H. Silverstein; Phyllis W. Speiser; Dennis M. Styne; Victor M. Montori

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Gilbert P. August, M.D. (*Chair*)—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: none declared; Grant or Other Research Support: none declared.

Sonia Caprio, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: none declared; Grant or Other Research Support: none declared.

Ilene Fennoy, M.D., MPH—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Novo Nordisk Turner's Syndrome Advisory Committee (2005); Grant or Other Research Support: Novo Nordisk Answer Program, Serono—Cod Click Adolescent Transition Study, Unimed—Androgel in Male Hypogonadal Puberty Study.

Michael Freemark, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: none declared; Grant or Other Research Support: none declared.

Francine R. Kaufman, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Medtronic, Lifescan, Omnipod, Mannkind, Novo Nordisk; Grant or Other Research Support: GSK, Medtronic.

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Janet H. Silverstein, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Advisory board member for the Genentech Center for Clinical Research in Endocrinology; Grant or Other Research Support: none declared.

Phyllis W. Speiser, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: none declared; Grant or Other Research Support: Speakers Bureau—Lilly, Pfizer, and Investigator—Lilly, Genetech, Novo Nordisk, Pfizer, Serono.

Dennis M. Styne, M.D.—Significant Financial Interests: none declared; Governance: none declared; Consultation or Advisement: Healthy Living Academy; Grant or Other Research Support: none declared.

\*Victor M. Montori, M.D.—Financial or Business/Organizational Interests: none declared; Significant Financial or Leadership Position: none declared; Consultation/Advisement: KER Unit (Mayo Clinic).

\*Evidence-based reviews for this guideline were prepared under contract with The Endocrine Society.

# **ENDORSER(S)**

Lawson Wilkins Pediatric Endocrine Society - Medical Specialty Society

#### **GUIDELINE STATUS**

This is the current release of the guideline.

Endocrine Society clinical guidelines are valid for 3 years, after which time they are revised.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from <u>The Endocrine Society</u>.

Print copies: Available from The Endocrine Society, c/o Bank of America, P.O. Box 630721, Baltimore, MD 21263-0736; Phone: (301) 941.0210; Email: Societyservices@endo-society.org

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

• McGovern L, Johnson JN, Paulo R, Hettinger A, Singhal V, Kamath C, Erwin PJ, Montori VM. Clinical review: treatment of pediatric obesity: a systematic

- review and meta-analysis of randomized trials. J Clin Endocrinol Metab. 2008 Dec;93(12):4600-5. Epub 2008 Sep 9. Review. Electronic copies: Available to subscribers of the Journal of Clinical Endocrinology & Metabolism Web site.
- Kamath CC, Vickers KS, Ehrlich A, McGovern L, Johnson J, Singhal V, Paulo R, Hettinger A, Erwin PJ, Montori VM. . Clinical review: behavioral interventions to prevent childhood obesity: a systematic review and metaanalyses of randomized trials. J Clin Endocrinol Metab. 2008 Dec;93(12):4606-15. Epub 2008 Sep 9. Review. Electronic copies: Available to subscribers of the <u>Journal of Clinical Endocrinology & Metabolism Web site</u>.

## **PATIENT RESOURCES**

The following is available:

 Patient guide to the prevention and management of pediatric obesity. Chevy Chase (MD): The Hormone Foundation; 2008 Dec. 2 p.

Electronic copies: Available in Portable Document Format (PDF) from <u>The</u> Hormone Foundation Web site.

Print copies: Available from The Endocrine Society, c/o Bank of America, P.O. Box 630721, Baltimore, MD 21263-0736; Phone: (301) 941.0210; Email: Societyservices@endo-society.org

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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